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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,442	03/07/2000	Gopinathan K. Menon	680.0035USU	1007

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EXAMINER

VENKAT, JYOTHSNA A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/521,442

Applicant(s)

MENON, GOPINATHAN K.

Examiner

JYOTHSNA A. VENKAT Ph. D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-11,14-21 and 23-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-11,14-21 and 23-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/18/05.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The examiner of this application is changed from Liliana Di Nola-Baron to **Jyothsna Venkat**.

The restriction requirement dated 12/31/02 is withdrawn. Claims 1-3, 5-11, 14-21 and 23-35 are pending in the application and the status of the claims are as follows:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-3, 5-11 and 14-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating acne using perilla oil, does not reasonably provide enablement for **preventing or treating or ameliorating cellulite using perilla oil or preventing** skin conditions selected from blemishes, breakout, oily skin, oily hair, oily scalp using perilla oil **or treating or ameliorating** condition selected from the group consisting of one or more blemishes, skin breakouts, cellulite, oily skin, oily hair, oily scalp using **PPAR stabilizer**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. See *In re Wands*, 858 F.2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1998). The court set forth the eight factors to consider when

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assessing if a disclosure would require undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546, the court recited eight factors

These factors include, but are not limited to:

- 1) *The breadth of the claims,*
- 2) *The nature of the invention,*
- 3) *The state of the prior art,*
- 4) *The level of one of ordinary skill,*
- 5) *The level of predictability in the art,*
- 6) *The amount of direction provided by the inventor,*
- 7) *The existence of working examples*
- 8) *The quantity of experimentation needed to make or use the invention based on the content of the disclosure.*

(1 and 2) *The breadth of the claims and the nature of the invention*: The claims are drawn to

(i) A method of treating or ameliorating a condition selected from the group consisting of one or more blemishes, skin breakouts, cellulite, oily skin, oily hair, oily scalp and any combination thereof, comprising topically applying to an affected area of the skin or hair a PPAR stabilizer in an amount effective to improve the aesthetic appearance of the affected area.

Or

(ii) A method of **preventing**, ameliorating or treating a condition selected from the group consisting of blemishes, breakout, cellulite, oily skin, oily hair, oily scalp, and a

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combination thereof, comprising topically applying perilla oil to an area of skin or hair affected by the condition in an amount effective to improve the aesthetic appearance of the condition.

Or

(iii) A condition resulting from or accompanied by an upregulation of PPAR receptors comprising: topically applying **perilla oil** to the condition, wherein the condition is selected from the group consisting of **cellulite**, oily skin, oily hair, oily scalp, and a combination thereof.

(3 and 5) The state of the prior art and the level of predictability in the art: The art teaches that in mammals there are multiple subtypes of PPAR called alpha, delta or gamma and only PPAR gamma is limited to adipose tissue and the art also teaches that the role of PPAR in adipocyte differentiation is likely to be complex, and the three receptors has highly divergent properties with respect to activation by peroxime proliferators and fatty acids. See U. S. Patent 6,004,751, col.12, lines 25-48. Applicants also admit at the filing of this application at page 1, under description of the related art that “ the role of metabolic pathway is still under investigation”. The art is therefore unpredictable to all the methods claimed using PPAR stabilizer or preventing the conditions using the PPAR stabilizer. Only one compound was described namely “ perilla oil “ for the treatment of acne”. Due to the unpredictability in the art, the claimed scope represents an invitation to experiment.

(6-7) The amount of direction provided by the inventors and the existence of working examples: Applicants have provided in the specification two examples, which are reproduced below:

EXAMPLE 1

Human skin cells were used to determine the effect upon PPAR upregulation by known PPAR agonists and the compound of the present invention as measured by relative PPRE (peroxisome Proliferator Response Element") activity. Preconfluent keratinocytes were transiently transfected with a PPRE-luciferase reporter construct together with a beta-galactosidase. Four similar groups of cells were treated the following day for 24 hours. The first group contained a vehicle having 0.05% dimethyl sulfoxide (DMSO). The second group was treated with G3, a PPAR alpha agonist. The group was treated with A4; perilla seed oil diluted 1:100 with DMSO. The fourth group was treated with G3 and A4. Figure 1 show, the addition of a PPAR agonist (G3) nearly doubled the PPRE activity as compared to the vehicle. The addition of perilla seed oil (A4) completely prevented the upregulation of PPAR in the presence of G3

EXAMPLE 2

As in Example 1, preconfluent keratinocytes were transfected with PPRE-luciferase and beta-galactosidase. Similar groups of cells were treated the following day for 24. The first group contained a vehicle having 0.05% DMSO. The second group was treated with A5; perilla seed oil diluted 1:100 with DMSO. The third group was treated with farnesol, PPAR activator. The fourth group was treated with farnesol and the fifth group was treated with an analog of clofibrate, a known PPAR alpha agonist. The sixth

group was treated with the clofibrate analog and A5. As the results illustrated in Figure 2 show, the addition of A5 to cells treated with the PPAR agonists significantly prevents PPAR upregulation. In fact, even in the presence of such agonists, A5 maintains PPARE activity in the range exhibited by the vehicle alone.

Only one compound namely Perilla seed oil (emphasis added) was tested. There is no testing for any other PPAR stabilizer and there is no nexus between these two examples and to the various conditions claimed. Additionally the examples did not demonstrate that perilla seed oil is useful for the prevention of various conditions. The examples also did not show the results for the treatment of cellulite. Note the etiology for cellulite is not same to that of acne.

(8) The quantity of experimentation needed to make or use the invention bases on the content of the disclosure: The claims recite method of treating or ameliorating or preventing various conditions using PPAR stabilizer or perilla seed oil. As explained supra, the instant specification gives one skilled in the art no indication that one could use **various PPAR stabilizers** and have a reasonable expectation of success for the **prevention, treatment of various conditions** or using perilla seed oil for the **prevention, ameliorating or treatment of cellulite**. Due to the unpredictability of the art and the role of PPAR metabolic pathway still under investigation, further testing would be necessary to use the claimed invention and the practice of the full scope of the invention would require undue experimentation.

3. Claims 21 and 23-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is new matter rejection.**

There is no support in the specification for the method claimed which is selected from the group consisting of b) reducing lipid synthesis in subcutaneous adipose tissue and c) reducing triglyceride synthesis in subcutaneous tissue by topically applying perilla oil.

In accordance with MPAP 714.02, applicants should specifically point out support for any amendments made to the disclosure.

4. Claims 14-15,21 and 22-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Clarification is requested for the concentration of linoleic acid based upon claims 14-15.

The recitation of “ means” for the recitation of Markush group is unclear and ambiguous. Deletion is suggested and amending to “ wherein the method” is to overcome the above rejection.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 1-3, 6-11, 14-18, 20-21, 23-24, 27-32 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of U. S. Patent 5,312,834('834) and 5,445,822('822).

Claim construction

Acne results in blemishes and acne also causes skin breakout and acne is caused by oily condition and therefore it is the position of the examiner that all these conditions are related and the art which teaches "treatment of acne" is also applicable to the conditions which can be "oily condition or blemishes or skin breakouts".

The instant application is claiming topically applying perilla oil for the treatment of acne and treating various conditions like oily skin or oily hair or oily scalp.

The patent '834 teaches pharmaceutical compositions using perilla oil for the treatment of acne. See col.1, see cols 3-4 and see the examples. The difference between the instant application and the patent is the instant application is claiming topical where as the art is teaching the same perilla oil using oral route of administration. However patent '822 teaches topical application using fatty acid triglyceride mixtures using alpha linolenic acid. See the abstract, see cols. 3-4. The patent teaches the concept of topical application of oils which have alpha linolenic acid. See claims.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare compositions of patent '834 and use it topically in view of patent '822 which teaches topical application of alpha linolenic acid. One of ordinary skill in the art would be motivated to prepare the compositions of '834 and use it topically with reasonable expectation of success that topical compositions absorb faster and one of ordinary skill in the art

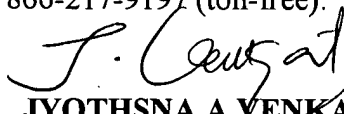
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would also have reasonable expectation of success that by using the compositions of '834 one could also expect reasonable expectation of success for treating oily condition, let it be skin or hair since there is nexus between the sebaceous gland and oily skin. With respect to claim 14 which excludes the range claimed in the patent '834 absent a showing the criticality of this claim to the range disclosed in the patent, the claims are rendered prima facie obvious over the combination of the patents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT Ph. D whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30: 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THURMAN K. PAGE can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JYOTHSNA A VENKAT Ph. D
Primary Examiner
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